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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,075	01/23/2004	Thomas Briese	5199-87	7998

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Brown Raysman Millstein Felder & Steiner LLP
163 Madison Avenue
P.O. Box 1989
Morristown, NJ 07962-1989

EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,075

Applicant(s)

BRIESE ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-32 and 34-38 is/are pending in the application.
4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6,8,9,25-32 and 34-38 is/are rejected.
7) ☒ Claim(s) 10 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 8, 25, 27, 29, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al US 2001/0053519, for the reasons given in the previous Office action. Applicant argues that Fodor discloses the theoretical idea of an array and provides a mathematical formula that gives a total of 1,048,576 nucleic acid sequences, and does not disclose the actual sequence of any of these nucleic acids. However, one of ordinary skill in the art could readily draw the structural formula of all of the 1,048,576 compounds in the generic 10-mer formula (although it would take a long time to write them down), and therefore any and all of the compounds can be at once envisaged. Furthermore, all of these nucleic acids are reduced to practice in Fodor's Example 2 on page 12. One skilled in the art may not have been able to tell which of the 10-mers in Fodor's array would match a coronavirus sequence, based on the disclosure of Fodor, but that is different from arguing that the 1,048,576 10-mers made by Fodor did not exist simply because their sequences were not individually written out.

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Claims 27 and 29 are now included in this rejection because these claims now require nothing more than the nucleic acid of claims 1 or 4; new claim 35 is included in this rejection because the array of all possible 10-mers would necessarily include multiple 10-mers meeting the limitations of claims 1 or 4.

Claims 1-6, 8, 9, 25-32, 34-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Rappuoli et al WO 2004/092360. The patent discloses primers and probes which meet the limitations of claim 1, see pages 185 and 633. The patent also discloses PCR methods for diagnosis, and fluorescent labels, see pages 185-193. These disclosures date back to priority document 60/463109, April 14, 2003, which is prior to applicant's filing date. See pages 141-145 of the priority application; the sequences designated 4031-4051 in the provisional are the same as the sequences designated 7332-7352 in the patent. See particularly the reference sequence AGCTCTCCCTAGCATTATTCACTGTAC (SEQ 4050 in the priority document), which has the sequence of applicant's SEQ ID NO:5 plus four additional terminal nucleotides.

Claim Rejections - 35 USC § 103

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fodor et al, for reasons of record. Applicant's arguments in regard to Fodor are addressed above.

Claims 1-6, 8, 9, 25-32, 34, 35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ksiazek et al (New England Journal of Medicine 348(20):1953-1966, published online April 10, 2003), Genbank Accession AY274119, and either Vabret et al (Journal of Virological Methods 97:59-66, 2001) or Stewart et al (In: Y. Becker and

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G.Darai, Eds, Diagnosis of Human Viruses by Polymerase Chain Reaction Technology, Springer-Verlag, New York (1995), pp. 316-327). Applicant argues a lack of motivation to combine Ksiazek and the Genbank locus with either Vabret or Stewart. This is not convincing, because Ksiazek, Vabret, and Stewart all address similar problems of detecting a coronavirus using PCR amplification, and the Genbank sequence remedies the deficiencies of the other references in providing the precise full genomic sequence of the new coronavirus of Ksiazek. Applicant argues that the references do not teach primers from the 3' noncoding region of a coronavirus. This is convincing for SEQ ID NO:2; however, the generic claims do not require this limitation, and therefore the generic claims remain rejected. Applicant argues the genetic distinction of SARS from other coronaviruses, and the fastidious nature of nucleic acid hybridization and amplification. However, the sensitivity of nucleic acid hybridization and the ability to amplify virtually any sequence is also well known. The Vabret reference does teach a preference for M gene primers; however, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. Vabret does teach successful detection using the N gene primers. Therefore, in the absence of unexpected results, it is maintained that the invention, as claimed, is obvious.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/14/06



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER